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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. RUTHIA HE, A/K/A/ RUJIA HE, and DAVID BRODY, Defendants.	No. CR 24-329-CRB GOVERNMENT'S RESPONSE TO DEFENDANT'S MOTION TO DISMISS COUNTS 1–6 OF THE INDICTMENT, OR, IN THE ALTERNATIVE, TO COMPEL DISCLOSURE OF GRAND JURY MATERIALS

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The Court should deny Defendant Ruthia He's motion to dismiss because it is inconsistent with *Ruan v. United States*, 597 U.S. 450 (2022), relies on a flawed argument rejected by almost every court, and misconstrues the Indictment. *See* ECF No. 157. Though there is no dispute that the Indictment tracks the language of the relevant statutes, alleges *mens rea*, and alleges the "without authorization" clause, Defendant wrongfully asserts that the Indictment must be dismissed because *Ruan* set forth a new pleading standard and the Indictment does not sufficiently allege *mens rea*. Both contentions are wrong.

First, *Ruan* rejected Defendant's present argument when it stated that "the Government need not refer to a lack of authorization (or any other exemption or exception) in the criminal indictment" alleging a violation of 21 U.S.C. § 841 (a)(1). *Id*. at 462. *Ruan* held that the lack of authorization was not an element of the offense, but that, under the burden-shifting provisions of the Controlled Substances Act ("CSA"), once a defendant met their burden of production by bringing forth evidence that the conduct was authorized, the Government had the burden of proof *at trial* to establish beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner.

Second, regardless, this Indictment sufficiently and plainly alleges what is required by *Ruan* at trial. The Indictment alleges in Counts 2 to 5 that Defendant "did knowingly and intentionally distribute and dispense . . . Schedule II controlled substances, not for a legitimate medical purpose in the usual course of professional practice." ECF No. 1 ¶ 76. The language satisfies "two constitutional requirements for an indictment: 'first . . . it contains the elements of the offense charged and fairly informs a defendant of the charge against which [s]he must defend, and, second . . . it enables h[er] to plead an acquittal or conviction in bar of future prosecutions for the same offense.'" *United States v. Resendiz-Ponce*, 549 U.S. 102, 108 (2007).

Defendant admits that the Indictment alleges *mens rea* (knowingly or intentionally), but asserts, as a matter of grammatical positioning, that the *mens rea* allegation does not apply to the authorization clause (not for a legitimate medical purpose in the usual course of professional practice) because the clause does not immediately follow the scienter allegation. In doing so, Defendant relies almost entirely on one district court opinion (from outside of this District). ECF No. 157 at 4 (citing *United States v. Wells*, 672 F. Supp. 3d 1066, 1071 (D. Nev. 2023)). The Court in *Wells* concluded that *Ruan*

added a "new element" and relied on Justice Alito's "concurrence in *Ruan*" to conclude that a *mens rea* allegation does not modify any clause that did not immediately follow. *Id*. at 1071. This Court should not adopt the reasoning of *Wells* because it is inconsistent with *Ruan*, more-recent Ninth Circuit precedent, and the decisions of other courts.

Wells is inconsistent both with the plain language of *Ruan* – that the authorization clause is "unlike an element" – and the majority's rejection of Justice Alito's argument based on "grammatical positioning." *Ruan*, 597 U.S. at 452, 466. *Wells* also erred because *Ruan* concerned whether a *mens rea* allegation could grammatically modify a *preceding clause*; here, the issue is whether the *mens rea* alleged in the Indictment modifies a *subsequent clause*. Under Supreme Court precedent, the answer is clear: the Indictment's allegation of "knowingly and intentionally" modifies every subsequent part of the sentence, including both the action (distributed and dispensed) and the lack of authorization (not for a legitimate medical purpose in the usual course of professional practice). *See Flores-Figueroa v. United States*, 556 U.S. 646, 650 (2009) ("As a matter of ordinary English grammar, it seems natural to read the statute's word 'knowingly' as applying to all the subsequently listed elements of the crime.").

The decision in *Wells* also is foreclosed by a Ninth Circuit decision last month in *United States v. Pham*, 120 F.4th 1368, 2024 U.S. App. LEXIS 28003 (9th Cir. Nov 5, 2024), which quoted with approval jury instructions that "explained that the government needed to prove . . . that the defendants intentionally distributed drugs outside the usual course of medical practice and not for a legitimate medical purpose." *Id*. at *10 (quoting *United States v. Hofschulz*, 105 F.4th 923, 929 (7th Cir. 2024)). The placement of the *mens rea* clause in that approved jury instruction is identical to the placement of the *mens rea* clause in the language of the Indictment here, and, as the Ninth Circuit quoted approvingly in *Pham*, even at the jury instructional phase, "*Ruan* requires nothing more." *Id.* Further, the Ninth Circuit noted that the *Ruan* requirements are about the government's burden of proof: only after the defendant met his "burden of producing evidence" in an affidavit "to rebut charges of unnecessary distribution" was the Government "required to prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." *Id*. at *12.

Defendant's hyperbolic assertions that the Indictment is "novel," a "striking example of overreach," and one that "alleges cause and effect, but not knowledge or intent," (ECF No. 157 at 1–2)

does not make it so. The Indictment contains straightforward allegations that Defendant was "conspiring to provide . . . stimulants that were not for a legitimate medical purpose in the usual course of professional practice" (¶ 56(a)) and "intentionally targeting drug-seeking patients" (¶ 56(a)). It specifies clinical policies that Defendant instituted to distribute unauthorized prescriptions (¶¶ 59–71) and alleges that she "persisted in the unlawful practices described [in the Indictment] after being made aware" of various facts sufficient to establish her knowledge that the policies were leading to unauthorized prescriptions, including Done being described as a "pill mill." *Id*. ¶ 72. The Indictment alleges both cause and effect (as well as aiding-and-abetting and conspiracy modes of liability), and knowledge and intent, and, at trial, the Government will prove that Defendant was warned her policies caused false diagnoses and unauthorized prescriptions, but knowingly and intentionally persisted to make money. Thus, the Government will prove at trial, consistent with *Ruan* and *Pham*, that Defendant knew she was generating prescriptions for and conspiring to prescribe narcotics without authorization.

Third, Defendant's arguments as to Count 1 fail as *Ruan* did not affect pleading requirements for conspiracy under 21 U.S.C. § 846. *Ruan* addressed only violations of 21 U.S.C. § 841(a)(1).

Defendant's other arguments are equally unavailing: the health-care fraud charge is sufficiently alleged; the requisite convergence exists between Defendant and her purpose in making fraudulent representations both directly to insurers, and indirectly to insurers via the false representations she made to pharmacies, as she made the false claims to pharmacies to cause them to continue dispensing Adderall prescriptions to Done members by billing insurance. Finally, *Ruan* provides no basis for Defendant's speculative request for grand jury testimony. The Court should deny the motion.

THE INDICTMENT

The Indictment alleges that Defendant owned Done, a "digital health company" that operated on a subscription model where individuals paid a monthly fee in exchange for prescriptions for Adderall and other stimulants. ECF No. 1 ¶¶ 48–50. Defendant held no medical license. She employed medical providers, including co-defendant Brody, who were authorized under certain circumstances to prescribe controlled substances, but only if the controlled substances were issued for a legitimate medical purpose in the usual course of professional practice. *See* 21 C.F.R. § 1306.04.

The Indictment charges Defendant with seven offenses, of which Defendant moves to dismiss Counts 1 through 6. Count 1 charges Defendant with conspiracy to distribute controlled substances. ECF No. 1 ¶¶ 54–74. The Count alleges that Defendants "did knowingly and intentionally combine, conspire, confederate, and agree together, and with other persons known and unknown to the Grand Jury, to knowingly and intentionally distribute and dispense mixtures and substances containing a detectable amount of controlled substances, including amphetamine-dextroamphetamine and other stimulants, Schedule II controlled substances, not for a legitimate medical purpose in the usual course of professional practice, in violation of Title 21, United States Code, Section 846." *Id.* ¶ 55.

The Indictment explains how Defendant agreed to knowingly and intentionally conspire, cause, and aid Done prescribers in distributing unauthorized controlled substances. The Indictment alleges that Defendant was "conspiring to provide . . . stimulants that were not for a legitimate medical purpose in the usual course of professional practice" (¶ 56(a)); "intentionally targeting drug-seeking patients" (¶ 56(a)) and intending to "use the comp structure to dis-encourage follow-up." *Id.* ¶¶ 56, 68. It details the steps that Defendant took to cause unauthorized prescriptions through (1) corporate formation (¶ 59); (2) advertising (¶ 61); (3) hiring (¶ 62); (4) screening (¶ 64); (5) "policies for initial telemedicine encounters" (¶ 65); (6) pressuring prescribers to write unauthorized prescriptions (¶ 67); (7) "polic[ies]" about "follow-up," "auto-refill" and compensation (¶ 68); (8) "bridge prescription policy" (¶ 69-70); (9) defrauding pharmacies, insurers, and other third parties (¶¶ 71, 72); and (10) obstructing justice in order to conceal and disguise the conspiracy (¶ 74). She "persisted in the unlawful practices described [in the Indictment] after being made aware that Done members were reading material posted on online social networks about how to use Done to obtain easy access to Adderall and other stimulants; Done members had overdosed and died; Done members described Done as a "straight up pill mill" and a "drug-pushing scam to sell ADHD drugs and make a lot of f****** money;" national media outlets reported that Done made Adderall and other stimulants too easy to obtain; and another company that prescribed Adderall and other stimulants via telemedicine . . . ceased prescribing Adderall and other stimulants on the same day that it was publicly reported that a Grand Jury issued a subpoena." *Id.* ¶ 72.

The Indictment follows with four substantive counts of unlawful distribution of controlled substances. *Id.* ¶¶ 75–76. The Indictment alleges that Defendant "did knowingly and intentionally

distribute and dispense, and aid or abet in the distribution or dispensing of, mixtures and substances containing a detectable amount of the listed Schedule II controlled substances, not for a legitimate medical purpose in the usual course of professional practice." *Id*. The Indictment alleges modes of liability under 18 U.S.C. § 2. *See* 18 U.S.C. §2(a) (causing) and §2(b) (aiding-and-abetting).

Count Six charges Defendant with conspiracy to commit health-care fraud. *Id*. ¶¶ 77–80. Defendant and her co-conspirators defrauded insurers through the submission of false claims for controlled substances that were medically unnecessary, fraudulent prior authorizations, and false representations to pharmacies to induce them to continue filling Done prescriptions and billing insurers. The purpose of the conspiracy was to make money for Done because Defendant knew that Done members would not continue "to pay subscription fees to Done" if insurers did not pay for the cost for the pharmacies to dispense Adderall and other stimulants to Done members. *Id*. ¶ 71.

LEGAL STANDARD

An indictment is sufficient if it "contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend." *United States v. Resendiz-Ponce*, 549 U.S. 102, 108 (2007) (quoting *Hamling v. United States*, 418 U.S. 87, 117 (1974)). "The test for sufficiency of the indictment is 'not whether it could have been framed in a more satisfactory manner, but whether it conforms to minimal constitutional standards." *United States v. Awad*, 551 F.3d 930, 935 (9th Cir. 2009). An indictment must provide sufficient notice to a defendant of what crime he or she has been charged with committing. *See, e.g., United States v. Bellot*, 113 F.4th 1151 (9th Cir. 2024); *United States v. Hartz*, 458 F.3d 1011, 1022 (9th Cir. 2006) ("The grand jury clause of the Fifth Amendment is designed to ensure that criminal defendants have fair notice of the charges that they will face and the theories that the government will present at trial."). When determining whether an indictment states a cognizable offense, courts are "bound by the four corners of the indictment, must accept the truth of the allegations in the indictment, and cannot consider evidence that does not appear on the face of the indictment." *United States v. Kelly*, 874 F.3d 1037, 1047 (9th Cir. 2017). The indictment "should be read in its entirety, construed according to common sense, and interpreted to include facts which are necessarily implied." *United States v. King*, 200 F.3d 1207, 1217 (9th Cir. 1999).

Ruan clarified the scienter requirement to establish a substantive violation of 21 U.S.C. § 841(a)(1) at trial. That statute reads, in part, that, "except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. § 841(a)(1). Dispensing a controlled substance is "authorized," and therefore excepted from the statutory prohibition, when "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); *Ruan*, 597 U.S. at 455.

This exception does not grant *carte blanche* to prescribe controlled substances. *See United States v. Moore*, 423 U.S. 122 (1975). "Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels" and "[i]was aware that [registered prescribers], who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *Id*. at 135.

Until *Ruan*, however, it was unclear whether the language "except as authorized" was an affirmative defense and courts were split over whether *mens rea* was evaluated based on an objective or subjective standard. *Ruan* held that "the statute's 'knowingly or intentionally' *mens rea* applies to authorization" and that "[a]fter a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so." *Id*. at 454.

The Supreme Court did not claim that the authorization clause was an element, but it held that it was "sufficiently like an element" in regard to the burden of proof at trial for the *mens rea* canon to apply. The Court rejected arguments in Justice Alito's concurrence that "grammatically speaking" the placement of "knowingly or intentionally" after the authorization clause "prevents the latter *mens rea* provision from modifying the former clause." *Id*. at 466. It reasoned that it had previously held that "a word such as 'knowingly' modifies not only the words directly following it, but also those other statutory terms that 'separate wrongful from innocent acts.'" *Id*. at 458. It also cited "analogous precedent" where "knowingly" modified both the" language following it and other language in the statute that "the use be 'not authorized.'" *Id*. at 460–61.

The *Ruan* Court was careful to explain that its decision had no impact on how the Government must plead the Indictment. Indeed, the CSA states that "[i]t shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, [or] indictment . . . ." 21 U.S.C. § 885(a)(1). The *Ruan* Court repeated: "[I]n a prosecution under the Controlled Substances Act, the Government **need not refer to a lack of authorization** [or any other exemption or exception] **in the criminal indictment**." *Ruan*, 497 U.S. at 462 (emphasis added). The Supreme Court also emphasized that a separate burden-shifting provision of the CSA "relieves the Government from having to disprove, at the outset of every Controlled Substances Act prosecution, every exception in the statutory scheme." *Id*. Further to that point, *Ruan* held that the Government did not need to prove "without authorization" until the defendant put it at issue by claiming that the prescriptions are authorized. Then the burden shifts to the Government *at trial*. *Id.* at 463.

ARGUMENT

I. The Indictment Sufficiently Alleges the Drug Distribution Offenses

A. *Ruan* Held That the Authorization Clause Is Not an Element That Needs to Be Alleged in the Indictment

Ruan provides no basis for dismissal. Procedurally, while *Ruan* clarified the scienter requirement for *proving* a case at trial, it expressly noted that "the Government need not set forth in an indictment a lack of authorization." *Ruan*, 497 U.S. at 451–52. In other words, the Government need not plead a knowing violation of the "except as authorized" requirement *at all*, much less with the specificity Defendant now demands.

Even so, Defendant asserts that post-*Ruan*, district courts in the Ninth Circuit have required that the Indictment allege the "without authorization clause," relying heavily on *Wells*. ECF No. 157 at 9.[1] But *Wells* – and prior precedent cited by Defendant – is inconsistent with *Ruan*. *Wells* incorrectly reasoned that the indictment was lacking because it was missing "the new element that *Ruan* added" and cited Ninth Circuit cases "before *Ruan*." *Wells*, 672 F. Supp. 3d at 1069 & 1071. But *Ruan*, in

[1] Defendant also cites *United States v. Spayd*, 627 F. Supp. 1058 (D. Alaska 2022), but *Spayd* did not cleanly reach the issue. The Court in *Spayd* noted that "[due to the recency of the Supreme Court's ruling in Ruan, the Court is largely without the benefit of other courts' interpretations of its implications" and "assume[d] that lack of authorization, even if it is something of a 'quasi-element,' must be pled in the indictment." In *Spayd*, however, the Court concluded that the Government sufficiently alleged authorization in the indictment.

fact, clarified that the authorization clause is unlike an element for the purposes of an indictment. And the Ninth Circuit law is clear that "where the reasoning or theory of our prior circuit authority is clearly irreconcilable with the reasoning or theory of intervening higher authority," the court is bound by the later and controlling authority, and consider the prior circuit opinion as having been effectively overruled. *Miller v. Gammie*, 335 F.3d 889, 893 (9th Cir. 2003). As the Court recognized in *Ruan*, Section 841(a)'s prefatory exception clause is unlike an element because it is subject to 21 U.S.C. 885(a)(1), which provides that "[i]t shall not be necessary for the United States to negative any exemption or exception . . . in any indictment." Instead, "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." As *Ruan* recognizes, Section 885(a)(1) makes Section 841(a)'s authorization clause relevant only when a defendant presents a claim that he falls within it, and the burden of proving a lack of authorization only shifts back to the Government when the defendant submits evidence of authorization, thus "reliev[ing] the Government from having to disprove, at the outset" a lack of authorization. *Ruan*, 497 U.S. at 451–52. Indeed, the concurrence in *Ruan* thought that the majority opinion should simply deem "without authorization" an affirmative defense. *Id.* at 469 (Alito, J., concurring). While the majority opinion did not go that far, it was perfectly clear that it was not a full element such that the Government must plead it in the indictment. *Id.* This debate emphasizes that *Ruan* addressed a *mens rea* that must be addressed and proven by the government *once the defendant claims to have acted in an authorized manner* and not before. Thus, logically, there can be no requirement that the Government predict a defense and address it in the indictment.

Indeed, other courts considering the same issue have denied motions to dismiss, rejecting the rationale in *Wells*, instead holding that *Ruan* is "about the government's burden of proof at trial, not the requirements of a valid indictment" and that since "the United States need not reference [defendant]'s lack of authorization in an indictment, then it logically follows that the United States is also not required to allege the associated *mens rea*—that he knowingly and intentionally acted in an unauthorized manner." *United States v. Fletcher*, 2023 U.S. Dist. LEXIS 106141, at *14 (E.D. Ky. June 20, 2023); *United States v. Goodman*, 2023 U.S. Dist. LEXIS 155058, at *7 (E.D. Pa. Sept. 1, 2023) ("[T]he mens rea language of section 841 requires the United States to prove beyond a

reasonable doubt—not plead—in its criminal prosecution the defendant knowingly or intentionally acted in an unauthorized manner"); *United States v. Hollington*, 2023 U.S. Dist. LEXIS 114376 (M.D. Fla. July 3, 2023); *United States v. Smith*, 2023 U.S. Dist. LEXIS 101212 (M.D. Tenn. Apr. 4, 2023). This is even more true because Defendant is not a medical professional. *United States v. Litwin*, 2023 U.S. Dist. LEXIS 151063, *6 (D. Nev. August 28, 2023) ("Courts that have held 'except as authorized' as an essential element have always done so through the lens of a legitimate medical practitioner.").

B. The Indictment Pleads Mens Rea Regarding Authorization

Although it is not required, the Indictment in this case *does* plead what *Ruan* ultimately may require the Government to prove at trial. The Indictment alleges Defendants "knowingly and intentionally" distributed controlled substances "not for a legitimate medical purpose in the usual course of professional practice." ECF No. 1 ¶ 76. Thus, even if applying the rationale advanced by Defendant, the Indictment is adequately pled and should not be dismissed.

Consistent with Rule 7, the Court must interpret the Indictment with regards to the plain, ordinary meaning of the words contained therein to avoid hyper-technical pleading requirements. *See* Fed. R. Crim. P. 7. The phrase "did knowingly and intentionally" alleges the required *mens rea* for each clause that follows, including both the distribution and "without authorization" clauses. *See Flores-Figueroa v. United States*, 556 U.S. 646, 650 (2009). Defendant relies on *Wells*, but *Wells* is inconsistent with Supreme Court precedent holding that the use of the phrase "knowingly" modifies subsequent clauses. In *Flores-Figueroa,* the Supreme Court explained:

> In ordinary English, where a transitive verb has an object, listeners in most contexts assume than an adverb (such as knowingly) that modifies the transitive verb tells the listener how the subject performed the entire action, including the object as set forth in the sentence. Thus, if a bank official says, "Smith knowingly transferred the funds to his brother's account," we would normally understand the bank official's statement as telling us that Smith knew the account was his brother's. Nor would it matter if the bank official said[,] "Smith knowingly transferred the funds to the account of his brother." In either instance, if the bank official later told us that Smith did not know the account belonged to Smith's brother, we should be surprised.

Flores-Figuroa, 556 U.S. at 650–51.

Wells found Justice Alito's grammatical rationale "notabl[e]" (*Wells*, 672 F. Supp. 3d at 1071), but that was rejected by the majority opinion. There, the Court found the CSA's *mens rea* applied to

the "except as authorized" clause even though the clause "does not immediately follow the scienter provision." *Ruan*, 597 U.S. at 461. The same is true for the Indictment, as "not for a legitimate medical purpose in the usual course of professional practice" does not *immediately* follow "knowingly and intentionally." But by reading the Indictment practically, liberally, and as the Supreme Court interpreted the statute, the "knowingly and intentionally" qualifier applies to the lack of authorization as well as the distribution.

As noted above, *Wells* also is inconsistent with Ninth Circuit's recent decision in *Pham*. In *Pham*, the Ninth Circuit affirmed the district court's denial of a motion to withdraw defendant's guilty plea to conspiracy to distribute controlled substances. Defendant argued that he was not apprised that *Ruan* requires the government to prove that he knew he was not authorized to issue the prescriptions. The Ninth Circuit rejected this argument, holding that "the agreement and colloquy clearly stated that Pham *knowingly issued prescriptions outside the usual course of professional medical practice and without a legitimate medical purpose*." *Id*. at *4 (emphasis added). *Pham* also referred approvingly to instructions to juries that they needed to find that defendant "knowingly or intentionally distributed controlled substances outside the usual course of professional practice and not for a legitimate medical purpose." *Id*. at *10–*11 (*quoting United States v. Titus*, 78 F.4th 595, 602 (3d Cir. 2023)). The language in the Indictment here mimics these jury instructions in other circuits that were cited approvingly in *Pham* and it therefore covers the knowing *mens rea* as required by the Ninth Circuit.[2]

Numerous district courts also have rejected the argument advanced by Defendant here and denied motions to dismiss nearly identical indictments.[3] Indeed, that the district courts have denied at

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[2] In the instant indictment, an appositive phrase separates the *mens rea* language ("knowingly and intentionally") and the unauthorized ("not for a legitimate medical purpose in the usual course . . .") language, which provides extra detail about the controlled substances ("including amphetamine-dextroamphetamine . . ., Schedule II controlled substances"). The appositive phrase does not otherwise alter or affect the grammar of the sentence.

[3] *United States v. Adelgass*, 2022 U.S. Dist. LEXIS 185964, at *4 (S.D.N.Y. Oct. 11, 2022) (denying motion to dismiss and calling the defendant's position "meritless"); *United States v. Henson*, 2024 U.S. Dist. LEXIS 3549, at *9 (D. Kan. Jan. 5, 2024) (denying motion to dismiss and holding that "[i]f the Supreme Court in *Ruan* could conclude that a knowing and intentional scienter requirement applies to the "except as authorized" clause preceding that scienter requirement in § 841, it seems no great stretch to think a fair reading of the indictment would apply the knowing and intentional scienter to the entirety of the actions thereafter."); *United States v. Taylor*, 2022 U.S. Dist. LEXIS 164807, at

(footnote cont'd on next page)

least six (*see* fn. 3) nearly identical motions to dismiss disproves Defendant's overheated assertion that "the Government has taken the position that the same language in the Indictment charging Ms. He is insufficient to plead *mens rea*." Mot. at 12–13. To the contrary, the Government has defended such indictments and courts nearly-uniformly—with apparently the sole exception of *Wells*—have rejected Defendant's position. Voluntary dismissals don't establish that the indictments in those cases were deficient, as many different factual circumstances may lead to voluntary dismissal, and Defendant extrapolates conclusions wholly absent from the records in those cases.[4] Nor can an out-of-context quote from an article establish a purported policy on indictment drafting.[5]

C. The Factual Allegations Track the Essential Elements

Defendant's challenge to the manner and means section of the Indictment, which describes in detail how Defendant acted as the ringleader of the conspiracy and directed it, likewise fails. As alleged in the Indictment, Defendant, as CEO, devised and implemented Done's operations to

*19–*20 (E.D. Ky. Sept. 13, 2022) (denying motion to dismiss, holding that "indictments must be read practically and liberally," and that "[b]y reading the Indictment practically, liberally, and as the Supreme Court interpreted the statute, the 'knowingly and intentionally' qualifier applies to the lack of authorization as well as the distribution."); *United States v. Och*, 21-CR-40026 (D. Mass. Jan. 31, 2023) (ECF No. 53) (denying motion to dismiss; "Ruan did not modify the pleading standards for indictments under the [CSA], but, rather, addressed what must be proved at trial" and "[o]ther courts addressing this question have reached the same conclusion") (internal citations omitted); *United States v. Rudin*, 19-CR-10040 (W.D. Tenn. Dec. 27, 2022) (ECF No. 257 at 8) (denying motion to dismiss and explaining "[defendant's] reasoning that *Ruan* impacts the sufficiency of the indictment is flawed" as "*Ruan* focused on the required proof for a conviction"); *United States v. Fletcher*, 2023 U.S. Dist. LEXIS 106141 at *16 (E.D. Ky. June 20, 2023) (denying motion to dismiss and holding that "the *Ruan* Court expressly rejected this reading of the statute" and that "this Court must conclude that the phrase 'knowingly and intentionally' applies both to his alleged distribution and dispensing and to his alleged knowledge that this prescription was unauthorized by law").

[4] Defendant relies on *United States v. August*, 21-CR-912-FM (W.D. Tex. Sept. 29, 2022), but the dismissal was attributed to a failure of proof, not a drafting issue in the indictment. In its motion, the Government explained the change in the law as when "a medical practitioner may be *convicted* under the [CSA]," not as one related to indictment drafting. *Id.* at 2. Moreover, the Government stated that "a key witness on an essential element is unavailable to testify at trial," causing a confrontation clause issue. *Id*. at 3. *United States v. Rattini,* 19-CR-0081 (S.D. Ohio) (July 21, 2022 Minute Entry; ECF No. 149) is silent on the reason for dismissal. In *United States v. Kim*, 20-CR-163 (W.D. Okla. July 29, 2022) (ECF No. 53), the Government explained that *Ruan* delineated what the Government must "prove"—not what the Government must charge—and it offered no explanation for *how* its 154-count indictment was defective in dismissing the case. *Id.* at 2.

[5] It is clear from the full text of the article that the authors were framing the outlier opinions in *Wells* and *Spayd* as just that. The article framed *Wells* as contradicting the universally accepted reading of *Ruan* as a "case about the [G]overnment's burden at trial"; nowhere in the article is *Wells* elevated as reflecting the accepted standard for the Ninth Circuit. *See* Alexis Gregorian, *Outside the Usual Course*: *Prosecuting Medical Professionals for Unlawful Prescription of Controlled Substances*, 72 DOJ J. Fed. L. & Prac. 37–38 (Mar. 2024). Nor could a district court opinion establish a standard for the circuit.

knowingly and intentionally distribute unauthorized Adderall prescriptions in order to make money. The manner and means paragraphs of the Indictment explain how the conspiracy was effectuated according to Defendant's plans and goals, including actively searching for providers who would ignore medical guidelines to pass out prescriptions to cater to customer satisfaction and devising company-wide policies and procedures with the intent of causing and aiding and abetting Done prescribers in writing those medically unnecessary prescriptions. The "knowingly and intentionally" scienter is repeated in each count; it doesn't need to be repeated in each sentence of the manner and means of an indictment in order for the indictment to be facially valid. Defendant also ignores that following the specific and detailed description of Defendant's policies, the Indictment alleges that Defendant persisted in these policies even after becoming aware that they were in fact leading to unauthorized prescriptions. ECF No. 1 ¶ 72. This sufficiently alleges Defendant's intent, particularly when coupled with the numerous allegations that Defendant conspired, made false and fraudulent representations, and sought to conceal and disguise the conspiracy by obstructing justice—all of which are actions by which a jury could conclude she acted with sufficiently knowledge and intent. *Id.* ¶¶ 73–74.

II. The Court Should Deny the Motion to Dismiss Count 6

A. Defendant is Incorrect that *Ruan* Applies to Health Care Fraud Conspiracy

Defendant argues that the Government cannot allege a conspiracy to commit health care fraud under 18 U.S.C. § 1349 unless its allegations satisfy the elements of 21 U.S.C. § 841. This argument is as unavailing as it sounds on its face.

Section 1349 provides that "[a]ny person who attempts or conspires to commit any offense under this chapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy." In Count 6, the United States tracks the language of the statute, and specifically alleges that the Defendants did "knowingly and willfully, that is, with the intent to further the objects of the conspiracy, combine, conspire, confederate, and agree with each other, and others known and unknown to the Grand Jury, to knowingly and willfully execute a scheme and artifice to defraud . . . Medicare, Medicaid, and Commercial Insurers," (*i.e.*, a scheme to commit health care fraud in violation of 18 U.S.C. § 1347). ECF No. 1 ¶ 78. This is all the Indictment was required to do, as it contains the elements of the charged crime in adequate detail to inform Defendant of the charge

and to enable her to plead double jeopardy in bar of a future prosecution for that same offense.

Defendant—citing no case law—asserts that Count 6 must satisfy *Ruan*. But Defendant's same assertion has been rejected by other courts because "*Ruan* concerned a materially different statute." *Francois v. United States*, 2024 U.S. Dist. LEXIS 119216, *13 (S.D. Fla. July 8, 2024) (citing *United States v. Agresti*, 2022 U.S. Dist. LEXIS 133640, *2 (S.D. Fla. July 27, 2022) ("*Ruan* dealt with the Controlled Substances Act, 21 U.S.C. § 841, and not the statutes at issue in this case, 18 U.S.C. §§ 1347 and 1349"); *Oppong v. United States*, 2024 U.S. Dist. LEXIS 21481, *5 (S.D. Ohio Feb. 7, 2024) ("*Ruan* does not, on its own terms, extend its conclusion to other provisions."). *Ruan* thus supplies no basis to dismiss Count 6 of the Indictment.

B. The Indictment Sufficiently Alleges False Statements and Omissions

Defendant makes an unfounded claim that the Indictment does not adequately allege a health care fraud conspiracy. This is incorrect. The Indictment alleges it was a purpose of the conspiracy for Defendant to "enable[e] Done members to obtain Adderall and other stimulants from pharmacies by defrauding pharmacies and Medicare, Medicaid, and the Commercial Insurers." *Id*. ¶ 56. Insurers would only pay for claims for prescription drugs that were "dispensed upon a valid prescription, medically necessary, and eligible for reimbursement." *Id*. ¶¶ 32, 38, 45. If insurance did not cover a prescription, a patient would be required to pay the full price of the drug to the pharmacy. Pharmacies also would not fill a prescription or bill insurance unless the prescription was issued for a legitimate medical purpose in the ordinary course of professional practice, and complied with state law. *Id*. ¶¶ 7–8, 12, 13, and 15–16.

The Indictment alleges that the conspiracy operated as follows: Defendant conspired with Done prescribers to issue prescriptions that were medically unnecessary and invalid. ECF No. 1 ¶¶ 56, 58–74. To defraud insurers, Defendant collected insurance information from Done members, submitted fraudulent prior authorizations to obtain insurance coverage for these medically unnecessary prescriptions, and created fraudulent documents, including patient records, to satisfy insurer requirements. *Id*. ¶ 71(a), (c), (e). Defendant also transmitted these medically unnecessary and invalid prescriptions and, in some instances, insurance information, to pharmacies in order to cause pharmacies to submit false claims for reimbursement to insurers and dispense the drugs at little or no cost to patients. *Id*. ¶ 71. When pharmacies questioned the legitimacy of the prescriptions, Defendant defrauded the

pharmacies to keep them billing insurance and dispensing drugs. *Id.* ¶ 71. The scheme was necessary because Done members would not pay subscription fees to Done if insurers did not "pay for the cost of these drugs" to be dispensed by pharmacies. *Id.* ¶ 72.

Defendant relies on an unpublished decision by a district court not in this circuit. ECF No. 157 at 18–20 (citing *United States v. Mattia*, 2024 U.S. Dist. LEXIS 98835 (D.N.J. June 3, 2023)). In *Mattia*, the court dismissed health care fraud counts because the Indictment failed to allege: (1) any misrepresentation; (2) how the false and fraudulent claims were caused to be submitted to the health plan and who submitted those claims; or (3) what, if any false or fraudulent statements or misrepresentations appeared on the claims, nor who made them (or what omissions occurred and who omitted them). *Id.* at *15.

This Indictment is distinguishable from *Mattia*. It alleges how the conspiracy operated: Defendant "collected . . . insurance information from Done members," (ECF No. 1 ¶ 71(a)) "caused Done members' insurance information to be transmitted to pharmacies," (*id.* ¶ 71(c), and provided Done members with unauthorized and invalid prescriptions, knowing and intending that Done members would take the prescriptions to pharmacies and cause the pharmacies to submit fraudulent insurance claims. It also alleges both Done prescribers and pharmacies entered into contracts not to submit, or cause the submission, of invalid prescriptions or medically unnecessary claims, such that each submission deceived insurers that the prescription was valid and claim medically necessary, when it was not. *Id.* ¶¶ 28-32, 35-38, 43-45. Indeed, three Done prescribers pled guilty to conspiring to defraud insurers by issuing unauthorized prescriptions to be filled at pharmacies and billed to insurance.

To the extent that *Mattia* stands for the proposition that a conspiracy to commit health care fraud cannot be predicated on mere allegations about medically unnecessary prescriptions, it is incorrect and this Court should not follow it. *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023). In *Anderson*, the Sixth Circuit affirmed a doctor's conviction for health-care fraud and rejected sufficiency arguments that "it was the pharmacies, not he, who billed Medicare and Medicaid, and argu[ments] that he did not know how the prescriptions would be paid for, nor did he personally profit." *Id.* at 770. The Court reasoned that the "evidence was sufficient to convict [defendant] of health care fraud because, *inter alia*, "[w]itnesses affiliated with Medicare and Medicaid testified that neither program would pay for claims

that were medically unnecessary," defendant "prescribed controlled substances to patients who filled those prescriptions at local pharmacies," and there was evidence that the controlled substances were "without a legitimate medical purpose and outside the usual course of professional practice." *Id.*; *see also id.* at 771 (citing *United States v. Webb,* 655 F.3d 1238, 1258 (11th Cir. 2011) (per curiam) (explaining that "the type of health care fraud here involved Webb's prescribing controlled substances for other than legitimate medical purposes, and having pharmacies submit claims for reimbursement to health insurers on the basis of his prescriptions.").

If that evidence is sufficient to convict for health care fraud, those same allegations are sufficient here to allege it. While Defendant relies on *Mattia* to contend that he is entitled to more details about how the claims are fraudulent, courts in this district have denied motions to dismiss that similarly argued that an indictment failed to include facts as to "how the prescriptions, supporting documentation. . . and claims to Medicare were false and fraudulent." *United States v. Sogbein*, 2012 U.S. Dist. LEXIS 155648, at *9 (N.D. Cal. Oct. 29, 2012). In *Sogbein*, the Indictment alleged that defendants "conspired to defraud Medicare by fraudulently prescribing [power wheelchairs] to Medicare beneficiaries who did not need them, and in many cases, who did not even want them." *Id.* at *3. The court rejected defendant's argument that such an allegation was insufficient, reasoning that the "United States is not required to allege the theories on which it will rely, nor include evidence upon which it will rely to prove the facts at trial." *Id.* at 9. The Court concluded that when it "examines the Indictment in its entirety, and construes it with 'common sense and practicality,'" the Indictment was sufficient to provide the Defendants notice of the crime charged. *Id.* (citing *Awad*, 551 F.3d at 936). The same is true here.

Further, the Indictment alleges two other theories, not at issue in *Mattia*. First, it alleges that Defendant defrauded pharmacies by making "false and fraudulent representations" to pharmacies "about Done's prescription practices" and "policies" to "cause the pharmacies to submit false and fraudulent claims." ECF No. 1 ¶ 72(d). It also alleges that Defendant directly "submitted and caused to be submitted false and fraudulent prior authorizations" and "created and caused to be created false and fraudulent documents, including patient records" relied on by insurers in deciding to pay claims. *Id.* ¶ 71. Unlike the defendant in *Mattia*, who was a sales representative, here Defendant owns the company issuing the prescriptions and conspired to defraud insurers to pay for them. These allegations provide Defendant

with sufficient additional detail, not present in *Mattia*, regarding the health care fraud conspiracy.

C. The Defense Convergence Argument Fails

Defendant next argues that the health care fraud theory alleged in the Indictment violates the convergence requirement for wire fraud.[6] In a wire fraud case, a defendant's "intent must be to obtain money or property from the one who is deceived." *United States v. Lew*, 875 F.2d 219, 875 (9th Cir. 1989). The Indictment passes that test. First, as discussed above, the Indictment alleges a theory that involves the direct submission of fraudulent prior authorizations to insurers. Second, the Indictment satisfies the convergence requirement in regard to Defendant's efforts to defraud pharmacies because the Indictment alleges that Defendant's misrepresentations to pharmacies were designed to cause them to continue dispensing medication by submitting false claims to insurers. Courts in the Ninth Circuit have rejected convergence arguments in similar cases involving deception through intermediaries, like these pharmacies, where the intermediaries were used to deprive the ultimate victims of money or property. *See, e.g., United States v. Ali*, 620 F.3d 1062 (9th Cir. 2010) (upholding convictions where the victim (Microsoft) was properly identified as the party deprived of money or property as part of the scheme to defraud, even where no specific false statements were made to the victim for at least part of the offense and monetary transfers also involved third parties); *United States v. Holmes*, 2020 U.S. Dist. LEXIS (N.D. Cal. Oct. 13, 2020), at *45–*46 ("To the extent Defendants believe allegations that a defendant deceived one party cannot be probative of an intent to defraud another, the Court cannot agree. There is no question that doctors may serve as conduits of information to their patients. That there must be 'at least some level of convergence between the fraud and the loss' does not make irrelevant all misrepresentations made to individuals other than those deprived of money or property.").

Defendant implies that she cannot be charged with health care fraud because although insurers were deprived of money or property, they didn't pay Done directly, and Done gained as a result of the insurers' losses only because the availability of insurance coverage caused members to continue paying subscription fees to Done. But there is no obligation to prove a convergence between the insurers' losses and Defendant's gain. Here convergence exists between the scheme to defraud insurers—albeit, in some

[6] Defendant does not cite any authority for the proposition that the convergence theory applies to the health care fraud statute.

instances intermediated—and insurers' loss of money or property, which is all that is required. Indeed, gain is not even an element of health care fraud and courts regularly affirm convictions where defendants do not bill the insurer and where defendants do not profit from the scheme to defraud. *See, e.g., Anderson*, 67 F.4th at 770–71 (affirming health-care fraud conviction of doctor when the pharmacies, not the doctor, billed Medicare and Medicaid and where the doctor did not profit from prescription reimbursement); *United States v. Bertram*, 900 F.3d 743, 749 (6th Cir. 2018) (affirming health-care fraud conviction of urinalysis testing company employees who caused laboratories to bill insurer for medically unnecessary tests); *Webb*, 655 F.3d at 1258 (affirming health-care fraud conviction of provider who prescribed unauthorized controlled substances and where pharmacies submitted claims based on his prescriptions).

III. Defendant Is Not Entitled to Grand Jury Materials.

The Supreme Court has "consistently. . . recognized that the proper functioning of our grand jury system depends upon the secrecy of grand jury proceedings." *Douglas Oil Co. of California v. Petrol Stops Nw.,* 441 U.S. 211, 218 (1979). Federal Rule of Criminal Procedure 6(e) requires that grand jury activities generally be kept secret. Defendant speculates that the Government gave an "erroneous legal instruction" and argues that the grammatical syntax of the Indictment justifies a breach of this general rule of secrecy prescribed by Rule 6(e). ECF No. 157 at 29–30.

But there is no evidence that the Government improperly instructed the grand jury on the law, especially considering that the indictment here tracks the statutory language for the offenses. And a mere allegation of an incorrect legal instruction does not invalidate an indictment or constitute the "strong showing of particularized need" necessary to breach grand jury secrecy. *Costello v. United States*, 350 U.S. 359, 363 (1956); *United States v. Sells Eng'g, Inc.*, 463 U.S. 418, 443 (1983).

On its face, the Indictment reveals that the grand jury found probable cause that both Defendant He and Defendant Brody acted "knowingly" and "intentionally," and the Indictment (even though it was unnecessary) expressly set forth the *Ruan mens rea* standard for the "authorized" exception. Thus, there can be no speculation that the grand jury indicted Defendant under an incorrect standard.

What is more, courts have rejected the type of argument advanced by Defendant. In *United States v. Goodman*, 2023 U.S. Dist. LEXIS 15508, at *12–*13 (E.D. Pa. Sept. 1, 2023), pharmacists charged with OxyContin distribution offenses sought production of grand jury transcripts, asserting

that, per *Ruan*, the indictment failed to allege their "subjective belief that they were knowingly and intentionally acting outside the course of a legitimate professional purpose" and that the CSA applied to non-pharmacists or non-doctors. In denying the request for transcripts, the court explained, "*Ruan* does not apply here . . . *Ruan* dealt with the Government's burden of persuasion under § 841 at trial. It did not alter any pleading standards." *See also United States v. Adelglass*, 2022 U.S. Dist. LEXIS 185964, at *6–*7 (S.D.N.Y. Oct. 11, 2022) (denial of request for grand jury transcripts for defendants indicted pre-*Ruan* and ruling "[w]hat the Government is able to prove at trial is one thing; how the grand jury was instructed is another"). *Cf. United States v. Litwin*, 2023 U.S. Dist. LEXIS 151063, at *10 (D. Nev. Aug. 28, 2023) (denying request for transcripts as to *mens rea* requirement for "except as authorized" because the court "does not view the 'except as authorized clause' as an essential element for prosecuting non-medical practitioners).

The case relied on by Defendant, *United States v. Way,* 2015 U.S. Dist. LEXIS 168419 (E.D. Cal. Dec. 15, 2015), is distinguishable because Defendant is not confronting a change in law since being charged. In *Way*, the court ordered production of a subset of the grand jury transcript because "[t]he Supreme Court's decision . . . altered the element of knowledge for the crimes charged" and separately, the Government identified the Food and Drug Administration as a victim, and "[t]his theory appear[ed] nowhere in the Indictment." *Id.* at *5, *14, *23. Even in the wake of *Ruan,* courts rejected similar arguments. *United States v. Taylor*, 2022 U.S. LEXIS 223194, n.1 (E.D. Ky. Dec. 9, 2022) (denying defendants' request for transcripts based on claim that "the Supreme Court's recent decision in *Ruan* bolsters their claim that the Government improperly instructed the grand jury" because "the indictment is facially valid post-*Ruan*" "even though the *mens rea* requirement has evolved since it was issued."). Accordingly, this is not the type of situation warranting a breach of grand jury secrecy.

CONCLUSION

For the foregoing reasons, Defendant's motion should be denied.

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Respectfully submitted,

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